

K081275  
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## 510(k) Summary for Surgical Mesh

### A. Sponsor

Boston Scientific Corporation  
Urology and Gynecology Division  
100 Boston Scientific Way  
Marlborough, MA 01756

AUG 27 2008

### B. Contact

Janet A. McGrath  
Principal Regulatory Affairs Specialist  
508-683-4726  
or  
Donna Gardner  
Director, Regulatory Affairs  
508-683-4398

### C. Device Name

Tradename: Surgical Mesh, (SIS)  
Common/usual name: Surgical Mesh  
Classification Name: (PAH)- Mesh, Surgical, Polymeric  
21 CFR 878.3300, Class II

### D. Predicate Device(s)

Tradename: Advantage® Transvaginal Mid Urethral Sling System  
Advantage Fit™ System  
Lynx ® Suprapubic Mid Urethral Sling System  
Obtryx® Transobturator Mid Urethral Sling System  
Prefyx PPS® System  
AMS MiniArc™ Sling System

Common/usual name: Surgical Mesh  
Classification Name: (PAH)- Mesh, Surgical, Polymeric  
21 CFR 878.3300, Class II

#### Premarket

Notification: Boston Scientific Corporation: K020110, K040787  
American Medical System, Inc.: K073703

### E. Device Description

The proposed device is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a knitted polypropylene monofilament fiber mesh body with polypropylene carriers, each are attached to separate ends.

#### Accessories

The proposed mesh sling configuration is packaged with other legally marketed accessories (e.g., Delivery Device; Class I exempt: 876.4730 Manual gastroenterology-urology surgical instrument and accessories).

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**F. Intended Use**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**G. Technological Characteristics**

The proposed device has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicate(s).

**H. Substantial Equivalence**

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed mesh is substantially equivalent to the predicate mesh in terms of intended use, technological characteristics, and performance characteristics tested. The proposed device is as safe, as effective, and performs as well as the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Ms. Janet A. McGrath  
Principal Regulatory Affairs Specialist  
Boston Scientific Corporation  
100 Boston Scientific Way  
MARLBOROUGH MA 01752

SEP 28 2012

Re: K081275  
Trade/Device Name: Surgical Mesh, (SIS)  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: PAH  
Dated: August 13, 2008  
Received: August 14, 2008

Dear Ms. McGrath:

This letter corrects our substantially equivalent letter of August 27, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

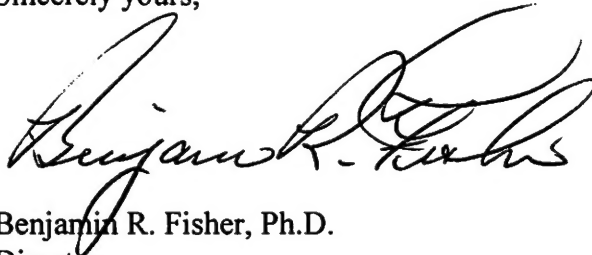
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over a horizontal line.

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K081275

**Indications for Use Statement**

**510(k) Number (if Known):** K081275

**Device Name:** Surgical Mesh , (SIS)

**Indications For Use:**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use   X    
(21 CFR 801 Subpart D)

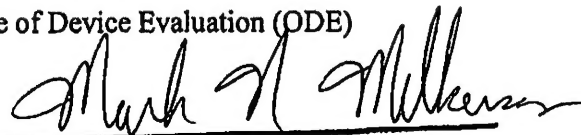
AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative,  
and Neurological Devices

510(k) Number           K081275